

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of group III in the reply filed on April 21, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The restriction requirement is still deemed proper and thereby made FINAL.

Claims 2-11, 13-15, and 19-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

### ***Specification***

The disclosure is objected to because of the following informalities: No title is given for the section describing the figures that accompany the application.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantial" in claim 1 is a relative term which renders the claim indefinite. The term "substantial" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The amount of degradation or denaturation that is permitted is unclear since no explanation is given as to what amount or functionality is equivalent to "substantial".

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morcol et al. (WO 02/064112 – see IDS) in view of Keller (U.S. Patent No. 6,726,924) and Baker et al. (U.S. Patent No. 6,534,018).

Morcol et al. teach a particulate composition where calcium phosphate, insulin, and polyethylene glycol (hydrophilic matrix) are combined as the core that is surrounded by the lipophilic casein (see page 24-26; instant claim 1). Morcol et al. go on to teach that these particles are sized in the range of 1-10  $\mu$ m and can be encapsulated in any conventional oral delivery system ( see page 21 lines 26-30; instant claim 1). Specifically, Morcol et al. teach the incorporation of multiple taught particles into gelatin capsules (gastric protection) (see page 12 line 30-page 13 line 2; instant claim 18) Morcol et al. do not teach the particles being in an additional lipophilic compound within the capsule.

Keller teaches a drug containing particulate lipophilic vector that is included with a liquid carrier in a gelatin capsule, where the capsule is coated with an enteric polymeric coating (see column 4 lines 22-29 and example 1; instant claims 1 and 18). Further Keller teaches that the gelatin capsules are negatively affected by the presence of water in the material they contain (see column 4 lines 5-6). Keller does not teach that this liquid carrier is lipophilic.

Baker et al. teach a drug containing lipophilic particulate composition that is taught to be delivered with a pharmaceutically acceptable carrier (see column 25 lines 14-27 and column 26 lines 3-4). Baker et al. go on to teach a set of oils that are particularly envisioned as such a carrier, where a variety of animal oils, mineral oils, and organic oils are named (see column 26 lines 6-10; instant claims 1 and 17). Since Baker teaches a hydrophobic/lipophilic material suitable as a carrier for the lipophilic particles taught by Morcol et al. and the use of a nonaqueous carrier in the taught gelatin was suggested, it would have been known to one of ordinary skill in the art at the time the invention was made to use a taught oil as a carrier of the Morcol et al. taught particles in the gelatin capsule. Therefore claims 1 and 17-18 are obvious over Morcol et al. in view of Keller and Baker et al.

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Thursday 8-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/  
Examiner, Art Unit 1615

/MP WOODWARD/  
Supervisory Patent Examiner, Art Unit 1615